

REMARKS

Claim 8 has been amended to make the description of the "recirculation fluid loop" consistent throughout the claim. Also, "heat exchanger" has been changed to --fluid exchanger--, a term which better characterizes the function performed by this feature of the claim (i.e., to controllably mix thermal reservoir fluid into the recirculation fluid loop).

I. REJECTION UNDER § 102(b)

The examiner has rejected claims 8-10 and 13 under 35 U.S.C. § 102(b) over the facts recited in the Information Disclosure Statement filed October 23, 1997. In particular, the examiner has indicated that:

The facts stated in the information disclosure statement, including the description in figure 7 of copending application 08/700,290, regarding the prototype are sufficient to establish that the invention described in these claims was on sale more than one year prior to the filing date.

35 U.S.C. § 102(b) provides that:

A person shall be entitled to a patent unless --

(b) the invention was . . . on sale in this country, more than one year prior to the date of application for patent in the United States.

Before the one year bar under §102(b) is triggered (1) "the invention" must have been on sale, and (2) there must be an actual sale or a definite offer to sell.

1. "THE INVENTION" WAS NOT ON SALE.

In Moleculon Research Corp. v. CBS, Inc., 229 USPQ 805, 809 (Fed. Cir. 1986), the Federal Circuit held that "assignment or sale of rights in the invention or potential patent rights is not a sale of 'the invention' within the meaning of § 102(b). The court justified this holding by concluding that it comported (1) "with the policies underlying the on sale bar," and (2) "with the business realities ordinarily surrounding a corporation's prosecution of patent applications for inventors." The policies underlying the on sale bar include:

- (i) discouraging removal of inventions from the public domain that the public justifiably believes are freely available;
- (ii) favoring prompt and widespread disclosure of inventions;
- (iii) prohibiting extension of the statutory period of exclusive rights; and
- (iv) providing a reasonable time after sales activity for

inventors to determine whether the invention warrants the expense of patenting.

See, e.g., Envirotech Corp. v. Westech Engineering Inc., 904 F.2d 1571, 1574 (Fed. Cir. 1990). An assignment or sale of rights in the invention does not amount to commercialization of the invention and, therefore, in view of the above policies, does not trigger the on sale bar. With a mere assignment or sale of rights: (i) the public cannot justifiably believe the invention is freely available; (ii) those most capable of exploiting such rights may use them and, thereby, disseminate to the public the ideas these rights encompass; (iii) the inventor is not affecting the competitive marketplace in a way that extends any exclusive rights to make, use and sell the invention -- rather, only the identity of the rights owner has changed; and (iv) the policy of encouraging the inventor to determine whether an idea is worth patenting is furthered because it provides the inventor with additional time in which to approach potential assignees without fear of triggering the on sale bar.

The facts recited in the Information Disclosure Statement filed October 23, 1997 amount to no more than an offer to assign or sell the inventors' rights in the prototype; consequently, the on sale bar of § 102(b) was not triggered. As recited in the Statement:

The inventors proposed to grant exclusive distributorship rights in a therapy unit to a company that would provide seed money which the inventors would use to manufacture commercial versions of their therapy unit. Alternatively, the inventors proposed to grant a company all right, title and interest in the therapy unit, including future patent rights, in exchange for a share of the proceeds of any commercialization or a lump sum payment.

The second proposal (to sell all right, title and interest in the therapy unit) did not trigger the on sale bar because the Federal Circuit in Moleculon Research held that this sort of proposal does not constitute a sale of "the invention" within the meaning of § 102(b). The first proposal (to grant exclusive distributorship rights) also did not trigger the on sale bar because, if an inventor's agreement to assign all right, title and interest in his invention, including future patent rights, does not amount to a sale of "the invention," surely, an offer to assign only one of the rights in the invention (i.e., the right to sell) cannot rise to the level of placing "the invention" on sale within the meaning of § 102(b).

For the foregoing reasons, we submit that the activities described in the

Information Disclosure Statement dated October 23, 1997, did not trigger the on sale bar under § 102(b), and that the rejection should be withdrawn.

2. **THERE WAS NO ACTUAL SALE OR DEFINITE OFFER TO SELL.**

As the Federal Circuit held in RCA Corp. v. Data General Corp., 887 F.2d 1056, 1062 (Fed. Cir. 1989), "where there is no sale, a definite offer to sell is an essential requirement of the on-sale bar The requirement of a *definite* offer excludes merely indefinite or nebulous discussion about a possible sale" (citation omitted; original emphasis). The above-mentioned activities relating to a possible distributor license or a possible assignment did not constitute an actual sale or a definite offer to sell the invention; rather, these activities amounted to no more than nebulous discussions about a possible sale. The inventors did not discuss any firm prices, quantities, royalty rates or lump sum payment amounts during any of the meetings with potential distributors/assignees. The character and purpose of these discussions was to determine merely whether there was any interest in the prototype to justify proceeding with further discussions. For these reasons, it is submitted that no firm or definite offer to sell the invention was made during any of the meetings referred to in the Statement.

For this additional reason, we submit that the activities described in the Information Disclosure Statement dated October 23, 1997, did not trigger the on sale bar under § 102(b), and that the rejection should be withdrawn.

II. REJECTIONS UNDER § 103(a)

The examiner has rejected claims 8-11 and 13 under 35 U.S.C. § 103(a) over Elkins (U.S. 4,691,762) in view of Fletcher (U.S. 3,744,555). With respect to claim 8, the examiner has indicated that:

Elkins et al. shows all of the features of claim 8 except that the control of the mixing of fluids is done manually, not automatically. However, Fletcher et al. is selected from a myriad of references that teach that temperature control in such thermal systems may be provided electronically, to eliminate the inaccuracies of human measurement. Hence, it would have been obvious to modify Elkins et al. to include electronic control, to eliminate human error.

Elkins, however, does not teach or suggest a fluid exchanger that controllably mixes thermal reservoir fluid into the recirculation fluid loop, nor does Elkins teach or suggest a control mechanism that adjustably controls the mixing of thermal reservoir fluid into the recirculation

fluid loop to control the temperature of the fluid circulating in the recirculation fluid loop, as recited in claim 8. To the contrary, in Elkins' temperature control system, the temperature source 56 is separated from the recirculation fluid loop and, therefore, there is no fluid mixing between the temperature source and the recirculation fluid loop (see, e.g., Figs. 32 and 33 and col. 17, lines 1-66 of Elkins' disclosure: temperature source 56 is contained inside a cavity 218, which is defined by a sealed liner 222, and fluid flows through the channel formed between insulating material 216, 217 and liner 222). Elkins does not teach or suggest that temperature source fluid should be mixed into the recirculation fluid loop. In fact, such a modification would defeat Elkins' objective "to enable convenient removal and replacement of the temperature source 56 in intimate heat exchange relation with the heat exchanger 18" (col. 7, lines 10-13). A modification that defeats an objective of Elkins' invention can hardly be said to be an obvious modification.

Fletcher also fails to teach or suggest a fluid exchanger that controllably mixes thermal reservoir fluid into the recirculation fluid loop, much less a control mechanism that adjustably controls the mixing of thermal reservoir fluid into the recirculation fluid loop to control the temperature of the fluid circulating in the recirculation fluid loop, as recited in claim 8. In Fletcher's system, fluid in the cooling loop 26 (Fig. 1) is cooled by flowing at least a part of the circulating fluid in a closed loop through the heat exchanger 22; there is no mixing of the circulating fluid with fluid inside the heat exchanger 22.

For the above reasons, applicants submit that the rejection of claim 8 over Elkins in view of Fletcher should be withdrawn. Claim 13 incorporates the features of claim 8 and is therefore patentable for at least the same reasons.

With respect to claim 9, the examiner has indicated that:

Claim 9 is rejected in that the combination mixes a predetermined volume of fluid.

But Elkins' system and Fletcher's system are both closed systems: there is no mixing of temperature source fluid into the recirculation fluid loop, as recited in the claims. The only mixing that occurs during operation of Elkins' system and Fletcher's system is the mixing between recirculation fluid that returns from the pad with recirculation fluid that flows through the heat exchanger. Thus, neither Elkins nor Fletcher, alone or in combination, teaches or suggests the invention recited in claim 9; this rejection should therefore be withdrawn.

With respect to claim 10, the examiner has indicated that:

Claim 10 is rejected in that Elkins allows for changes in the rate of flow of the device, which also changes the pressure.

After reviewing Elkins' disclosure, however, we could not identify any teaching or suggestion that Elkins' pump is configured to enable "adjustable control of fluid pressure in said therapy pad," as recited in claim 10. We ask that the examiner kindly point out where such a teaching or suggestion might be found in Elkins, or withdraw the rejection.

With respect to claim 11, the examiner has indicated that:

Claim 11 is rejected in that, as such, the pressure varies, providing tactile stimulation.

After reviewing Elkins' disclosure, however, we could not identify any teaching or suggestion of a control mechanism "adapted to vary pressure of recirculating fluid within said therapy pad in a manner to apply tactile stimulation to a therapy site by increasing and decreasing fluid pressure inside said therapy pad," as recited in claim 11. We ask that the examiner kindly point out where such a teaching or suggestion might be found in Elkins, or withdraw the rejection.

In addition, claims 9-11 incorporate all of the features of claim 8 and are therefore also patentable for the reasons given above with respect to claim 8.

The examiner has rejected claims 12 and 14-18 under 35 U.S.C. § 103(a) over Elkins in view of Fletcher and further in view of French (U.S. 4,844,072). But French does not teach or suggest a fluid exchanger that controllably mixes thermal reservoir fluid into the recirculation fluid loop, much less a control mechanism that adjustably controls the mixing of thermal reservoir fluid into the recirculation fluid loop to control the temperature of the fluid circulating in the recirculation fluid loop, as recited in independent claim 8. Thus, claims 12 and 14-18, which incorporate the features of claim 8, are patentable for at least the same reasons discussed above in connection with claim 8.

Applicants submit that all claims are in condition for allowance and should now be allowed.

Please apply any excess charges or any credits to Deposit Account No. 06-1050.

Respectfully submitted,

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